Citation:

Howe PR, Jureidini KF, Smith RM. Sodium and blood pressure in children – a short-term dietary intervention study. *Proc Nutr Soc Aust.* 1985; 10: 121-124.

Study Design:

Non-randomized control trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To conduct a preliminary dietary intervention study in school children aimed at identifying cardiovascular parameters that could be affected by changes in their sodium intake and might be useful for the diagnosis of pre-hypertensive, sodium-sensitive individuals
- To determine the feasibility of modifying sodium intake in children over a short period and the resultant effects on blood pressure (BP).

Inclusion Criteria:

Children whose BP was equal to or exceeded the 90th percentile after adjustment for age and height.

Exclusion Criteria:

Children whose BP was less than the 90th percentile after adjustment for age and height.

Description of Study Protocol:

Recruitment

Blood pressure was measured in a preliminary screening of 376 children ages 11 to 14 years attending an independent school. Children identified with BP greater than or equal to the 90th percentile for age were invited to participate in this dietary intervention study.

Design

- Three males and eight females followed a low-sodium (Na) diet for three weeks then switched to a high-Na diet for three weeks
- Seven males and three females followed a high-Na diet for three weeks then switched to a low-Na diet for three weeks
- Overnight urine collections were analyzed once a week

- Blood pressure was measured in supine and standing positions and after immersion of hand in cold water for two minutes (cold pressor test) was taken at baseline, three and six weeks.

Dietary Intake/Dietary Assessment Methodology

- Parents and children were interviewed individually by a dietitian who provided detailed instructions and advice on foods and food preparation appropriate for each diet
- Children were urged to achieve as large a difference in sodium intake as possible between the two diet periods
- Compliance was assessed from a 24-hour diet diary taken to assess Na, potassium (K), and energy intake based on food composition tables during each three-week period (and from measurements of sodium excretion in overnight urine samples weekly).

Intervention:

- Subjects followed a low-sodium diet for three weeks then switched to a high-sodium diet for three weeks
- Other subjects followed a high-sodium diet for three weeks then switched to a low-sodium diet for three weeks
- Instruction was given by dietitian but no information concerning amount of sodium to be reduced; subjects were told to reduce Na "as much as possible."

Statistical Analysis

Student's T-test and paired T-test.

Data Collection Summary:

Timing of Measurements

- Standing, supine and cold pressor blood pressures were taken at baseline, three and six weeks
- 24-hour dietary recalls were done at three and six weeks
- Overnight urines were measured weekly.

Dependent Variables

- Variable 1: Standing BP
- Variable 2: Supine BP
- Variable 3: BP after cold pressor test
- Variable 4: Heart rate (HR)
- Variable 5: Urine Na (UNa), and urine Na:K ratio excretion
- Variable 6: Energy intake.

Systolic (SBP) and diastolic blood pressure (DBP) readings (corresponding to Korotkoff sounds I and IV) were taken using a mercury sphygmomanometer with an appropriately sized cuff.

Independent Variables

Low Na diet.

Control Variables

- Age
- Height.

Description of Actual Data Sample:

- *Initial N:* N=21 (11 males, 10 females)
- *Attrition (final N):* There was no attrition
- *Age:* 11 to 14 years, mean age, males 12.6±0.2 years; females 12.6±0.3 years
- *Anthropometrics:*
  - Boys selected for the study were heavier than population screened
  - There was no difference in weight for girls
- *Location:* Independent school in Adelaide, South Australia.

Summary of Results:

Key Findings

- 24-hour dietary recalls indicated a three-fold decrease in Na intake on low-Na diet
- Sodium excretion values from final urine samples in each diet period reflect a slightly less than a two-fold difference in Na intake between the high- and low-sodium diets
- With the low sodium diet, food intake was reduced by one-third with no change in body weight and the Na: K ratios indicate that sodium intake was selectively reduced (this reduction was greater in girls than boys)
- There was a significant difference between the two diet periods in the level of DBP in the girls (supine and after cold pressor test) (P<0.05).

Assessment of Dietary Intervention

	After High-Na Diet		After Low-Na Diet	
	M (11)	F (10)	M (11)	F (10)
Energy intake (kcal per day x 103)	2.9 ±0.5	3.3±0.4*	1.9±0.1	1.9 ±0.1
Na intake mmol per day (estimated from diet)	187±15	219±19	74±9**	59±7**
Intake ratio (Na/K)	3.0±1.0	2.7±0.7	1.1±0.2	0.9±0.1*
Na excretion (mmol per day)§	222±35	132±14	125±22*	76±11**
Excretion ratio (Na/K)	2.8±0.3	3.2±0.2	1.9±0.4	1.5±0.3

(Significantly different from high Na values: *P<0.05, **P<0.01, Student's T-test.)

§Derived from Na/Creatinine ratio in overnight urine samples, using age- and sex-adjusted creatinine excretion data.

Effects of Sodium on Blood Pressure and Heart Rate

		After High-Na Diet		After Low-Na Diet	
		M (11)	F (10)	M (11)	F (10)
	Supine	79±2	76±2	81±2	71±3*

Diastolic blood pressure (mmHg)	Cold pressor test	100±3	92±2	101±3	83±3*
Systolic blood pressure (mmHg)	Supine	118±4	114±3	119±3	113±3
	Cold pressor test	129±4	121±3	134±3	120±3

*Significantly different from high Na value; P<0.05.

Author Conclusion:

- Small but significant reductions of DBP during the low sodium diet period were seen in girls only
- Only girls in study managed to reduce their sodium intake (based on the excretion data rather than the dietary estimates) below 100 mmol per day
- Feedback of information from the UNa measurements might prove useful for attaining greater adjustments of sodium intake in future intervention studies.

Reviewer Comments:

Checklist Comments

- *2.3: Health demographics other than BP and weight were not described*
- *2.4: This was a very small sample size; however, it most likely represents children in the 90th percentile for age because 376 were screened and only 21 were identified. However, this is assumed since there are 21 in the study but the authors did not state if all the students identified in the screening with higher BP consented to participate in the study.*
  - *Boys in the study group were heavier than their counterparts in the screened population*
  - *Method of assigning subjects to first or second period for low-Na diet were not described*
  - *Subjects served as their own control*
  - *Self-reported dietary recall data.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	???
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	???
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes

4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	No
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	???
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes

7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	???
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	???
8.1.	Were statistical analyses adequately described and the results reported appropriately?	No
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	???
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	???
10.2.	Was the study free from apparent conflict of interest?	Yes